European Commission

Draft Assessment Report prepared according to the Commission Regulation (EU) N° 1107/2009

BAS 750F
(Mefentrifluconazole)

Volume 3 – B.6 (PPP) – BAS 750 01 F

Rapporteur Member State : United Kingdom
Co-Rapporteur Member State : France & Austria

Version History

When	What
April 2017	Initial DAR

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B.6. TOXICOLOGY AND METABOLISM DATA AND ASSESSMENT OF RISKS FOR HUMANS

Since the ISO proposed name of menfentrifluconazole has not been confirmed at the time of this evaluation, the active substance will be referred to as BASF 750 F throughout this report.

The representative formulation BAS 750 01 F is an EC (emulsifiable concentrate) that contains 100 g/L of the active substance BAS 750 F. All the *in vivo* studies presented used the same batch of product (Batch: FD-140113-0006), which contained 9.9 % of the active substance.

B.6.1. ACUTE TOXICITY OF PLANT PROTECTION PRODUCT

In accordance with Regulation 284/2013, the data requirements for toxicological assessment of plant protection products offer the possibility to avoid animal testing where an alternative approach under Regulation (EC) 1272/2008 can be justified by the applicant. Since BAS 750 01 F is to be registered also outside Europe, the applicant performed toxicological studies with the product on vertebrates to meet the regulatory requirements of those regimes. The applicant therefore presented both *in vivo* toxicological tests with the product and predictions of its classification from the use of the calculation method, as allowed under CLP. The RMS has provided data protection for *in vivo* studies only when a decision on classification and labelling was made solely on the results of those studies.

B.6.1.1. Oral

The acute oral toxicity of BASF 750 01 F has been investigated by the acute-toxic-class method.

Table B.6.1.1. Summary of the acute oral toxicity of BAS 750 01F

Method Guideline, GLP status, reference	Species, strain, sex, no./group	Test substance, dose levels, duration of exposure	LD50	Remarks
OECD 423 (2001) (acute toxic class method) GLP Report CP 7.1.1/1 [redacted] 2015a (2014/1170774)	Rats / Wistar / 3 females / group (6 animals total) Observation period: 14 days	2000 mg/kg bw	> 2000 mg/kg bw	No deaths. Clinical signs included: impaired general state and piloerection between 1 & 5 hours after administration. Weight gain within the normal range for all animals throughout the study period. No adverse macroscopic necropsy findings

In an acute toxic class study, 2000 mg/kg bw of the product BAS 750 01 F was administered to three fasted female rats. No deaths occurred in this group .This result was confirmed by administering the same dosage to another group of 3 females. Again, no deaths occurred.

The observed clinical signs, which included impaired general state and piloerection between 1 and 5 hours after administration, were indicative of general toxicity but did not indicate specific target organ toxicity. All the observed clinical signs of toxicity had resolved by the end of the day of dose administration. There were no macroscopic pathological findings in any of the animals. Weight gain was within the normal range for all animals throughout the study.

In this study, BAS 750 01 F was not acutely toxic by the oral route (LD50 > 2000 mg/kg bw) and thus did not meet the criteria for classification.

Data on the acute oral toxicity of all components was available, with LD50 values > 2000 mg/kg bw in all cases. The applicant thus predicted an LD50 > 2000 mg/kg bw for the product.

B.6.1.2. Dermal

The acute dermal toxicity of BASF 750 01 F has been investigated in rats.

Table B.6.1.2. Summary of the acute dermal toxicity of BAS 750 01F

Method **Guideline, GLP status, reference**	**Species, strain, sex, no./group**	**Test substance, dose levels, duration of exposure**	**LD50**	**Remarks**
OECD 402 (1987) GLP Report CP 7.1.2/1 [redacted] 2015b (2014/1170776)	Rat, Wistar, 5/sex Observation period: 14 days	5000 mg/kg bw	> 5000 mg/kg bw	No deaths. Local effects (1 female): well-defined erythema (grade 2, days 1 to 2; grade 1 on day 3); scaling & incrustations (day 3). No systemic or local effects in other animals.

In an acute dermal toxicity study, animals were exposed to a single dose of 5000 mg/kg bw of BAS 750 01 F for 24 hours under a semi-occlusive dressing. The area exposed to the test item totalled at least 10 % of the total body surface area. Following the 24-hour exposure period , the dressing was removed and the exposed area was rinsed with water. No deaths were recorded during the study period, nor were there any signs of systemic toxicity. In one female animal local effects were noted up to day 3; these comprised erythema, scaling and incrustations. No local signs were noted in the other animals. Weight gain was normal throughout the study period in all animals.

Therefore, BAS 750 01 F was not acutely toxic by the dermal route in this study (LD50 > 5000 mg/kg) and does not meet the criteria for classification.

Data on acute dermal toxicity was available for 71 % of the components, with LD50 values > 2000 mg/kg bw in all cases. The other components were not classified for skin irritation. On this basis, the applicant predicted that the dermal LD50 for the product would exceed 2000 mg/kg bw.

B.6.1.3. Inhalation

The acute inhalation toxicity of BASF 750 01 F has been investigated in rats.

Table B.6.1.3. Summary of the acute inhalation toxicity of BAS 750 01F

Method Guideline, GLP status, reference	**Species, strain, sex, no./group**	**Test substance, dose levels, duration of exposure**	**LC50**	**Remarks**
OECD 403 (2009) GLP Report CP 7.1.3/1 [redacted] 2014 (2014/1170778)	Rat, Wistar, 5/sex Nose-only exposure Observation period: 14 days	2.4 and 5.4 mg/L air Mist (liquid aerosol) 4 hour exposure Mass median aerodynamic diameters (MMADs) Group 1: 2.35µm – 2.41 µm Group 2: 1.87 µm - 1.89 µm	5.4mg/L < LC50 > 2.4 mg/L	**5.4 mg/L:** Death of 3/5 males (day 3) and 4/5 females (days 2, 7, 13). Clinical signs: decreased activity, ruffled fur, laboured breath, breathing noises and salivation. Macroscopic examination: reddish discolouration of lungs & mandibular lymph nodes, sore skin, beginning of autolysis, intestines distended with gas. **2.4 mg/L:** Death of 1 female (day 14). Clinical signs: ruffled fur, laboured breath, breathing noises and salivation. Macroscopic examination: 1 female showed intestines distended with gas and and beginning to show autloysis.

In an acute inhalation study, two groups of 10 rats were exposed by nose-only, flow-past inhalation for four hours to the test item at chemically-determined mean concentrations of 2.4 and 5.4 mg/L. Three males and four females died after exposure to 5.4 mg/L air, whilst one female died after exposure to 2.4 mg/L. Clinical signs at both concentrations consisted of decreased activity, ruffled fur, laboured breath, breathing noises and salivation. Macroscopic examination of the high-concentration animals showed reddish discolouration of the lungs and mandibular lymph nodes, sore skin, the beginning of autolysis and intestines distended with gas; the latter observation was also reported in one female at 2.4 mg/L. These findings were most likely to be attributable to the onset of decay processes rather than a direct result of exposure to the test material. At both concentrations, body-weight loss or stagnation of body-weight gain was noted after exposure.

Based on this study, the LC_{50} was between 2.4 and 5.4 mg/L air. The RMS therefore concludes that BAS 750 01 F meets the criteria for acute inhalation toxicity category 4 ($1 < LC50 \leq 5$ mg/L) (H332).

One of the co-formulants, which is present at 1 %, has a classification for acute inhalation toxicity category 4 (H332). Since two major components, comprising approximately 30 % of the product, do not have acute-inhalation toxicity data, the applicant concluded that a robust prediction for this end-point based on the calculation method could not be made. Since the proposed classification was based on the acute inhalation toxicity study, the RMS will provide it with data protection.

B.6.1.4. Skin irritation

An initital assessment of the skin irritation potential of BAS 750 01 F was made in two *in vitro* assays. In addition, an *in vivo* acute dermal irritation/corrosion study was performed in rabbits.

Table B.6.1.4. Summary of studies to investigate the skin irritation potential of BAS 750 01 F

Method Guideline, GLP status, reference	**Test system**	**Test substance, dose levels, duration of exposure**	**Results**
EpiDerm skin irritation test OECD 431, 439 Not GLP Report CP 7.1.4/2 Wareing 2014b (2014/1127441)	Human reconstituted epidermis model	30 µL of BAS 750 01 F Exposure for 1 hour with 42 hours' post-incubation period Positive control: 5 % SDS	Tissue viability values: BAS 750 F 750 01 F = 3 % of negative control values Positive control = 3 % of the negative control values. Skin irritant under the conditions of this study
EpiDerm skin corrosion test OECD 431 Not GLP Report CP 7.1.4/1 Wareing 2014a (2014/1127439)	Human reconstituted epidermis model	50 µL of BAS 750 01 F Exposed for 3 minutes and 1 hour Positive control: 8 N KOH	Tissue viability values at 3 minutes: BAS 750 F 750 01 F = 116 % of the negative control value Positive control = 20 % of the negative control value Tissue viability values at 1 hour: BAS 750 F 750 01 F = 81 % of the negative control value Positive control = 7 % of the negative control value Not corrosive under the conditions of this study
Acute dermal irritation / corrosion in rabbits OECD 404 GLP Report CP 7.1.4/3 [redacted] 2015c (2014/1170779)	Rabbits, New Zealand White, 3 Females	0.5 ml of BAS 750 01 F Exposure period: 4 hours Observation period: 14 days	Mean scores over 24, 48 and 72 hours for each animal: Erythema = 2.0, 2.3 and 2.3 Oedema = 0.7, 1.3 and 0.3 Not reversible in all animals within 14 days Potential skin irritant under the conditions of this study

In an *in vitro* test with human reconstituted epidermis, BAS 750 01 F demonstrated a skin irritation potential (mean tissue viability ≤ 50 % of the negative control). In a similar *in vitro* test to investigate the product's skin corrosion potential, mean tissue viability values at 3 minutes of ≥ 50 % of the negative control and at one hour of ≥ 15 % of the negative control indicated that BAS 750 01 F was not corrosive under the conditions of this assay. On the basis of these results and in accordance with OECD guidance[1], the product can be classified as a skin irritant in category 2 (H315).

The acute dermal irritation and corrosion potential of BAS 750 01 F was additionally assessed *in vivo* in rabbits. Mean scores over 24, 48 and 72 hours for each animal were 2.0, 2.3 and 2.3 for erythema and 0.7, 1.3 and 0.3 for oedema. At study termination (14 days), reactions were still noted in all three of the animals, comprising well-defined to moderate erythema, slight oedema and scaling. Based on a mean value of ≥ 2.3 for erythema in two animals and persistence of the inflammation in three animals, the product meets the criteria for classification as a skin irritant category 2 (H315) in accordance with the CLP regulation.

Data on skin irritation potential are available for all the ingredients of the product. The active substance is not a skin irritant. However, the formulated product contains three components, which

[1] ENV/JM/MONO(2014)19. Guidance document on an integrated approach on testing and assessment (IATA) for skin corrosion and irritation.

together comprise 45 % of the composition, that are classified as skin irritants (category 2). The applicant therefore used the additivity approach to predict that the product would meet the criteria for classification as as skin irritant category 2.

B.6.1.5. Eye irritation

The eye irritation potential of BASF 750 01 F has been investigated in an *ex vivo* study, an *in vitro* study and an *in vivo* study in rabbits. The applicant's standard test strategy in the case of a positive *in vitro* EpiOcular test is to proceed with sequential *in vivo* eye irritation tests to check for the absence of eye-damaging properties.

Table B.6.1.5. Summary of the eye irritation studies with BASF 750 01 F

Method Guideline, GLP status, reference	**Test system**	**Test substance, dose levels, duration of exposure**	**Results**
Bovine corneal opacity and permeability test (BCOP test) OECD 437 Not GLP Report CP 7.1.5/1 Wareing, 2014c (2014/1127440)	Three bovine corneas	750µL of undiluted BASF 750 01 F Exposure period = 10 minutes Post-incubation period = 2 hours Positive control = 100% dimethylformamide Negative control = deionised water	Mean *in vitro* irritancy scores (IVIS): BAS 750 01 F = 7.8 ± 2.1 Negative control = 2.2 ± 3.7 Positive control = 129.2 ± 12.0 Histological evaluation = score of III (moderate) for BAS 750 01 F Not corrosive or severe eye irritant in this test
EpiOcular Eye Irritation Test No test guidelines Not GLP Report CP 7.1.5/2 Remmele, 2014a (2014/1083341)	Two EpiOcular tissue samples	50µL of undiluted BASF 750 01 F Exposure period = 30 minutes Post-incubation period = 2 hours Positive control = 98% methyl acetate Negative control = deionised water	Mean OD570 values (% of negative control: BAS 750 01 F= 7 ± 2.3 Negative control: 100 ± 6.3 Postive control: 26 ± 2.10 Potential eye irritant under the conditions of this study.
Acute eye irritation in rabbits OECD 405 (2002) GLP Report CP 7.1.5/3 [redacted], 2014d (2014/1170780)	Rabbit, New Zealand White, 3 females (step-wise procedure)	0.1 ml of undiluted BASF 750 01 F in one eye for 24 hours, followed by rinsing with tap water. Observation period = 28 days	Mean scores (averaged over 24, 48 & 72 hours) for each animal: Corneal Opacity: 2.0, 1.3, 1.0 Iris lesions: 1.0, 1.0, 0.7 Conjuctiva Redness: 1.0, 1.0, 1.0 Chemosis: 1.0, 1.0 ,1.0 All reactions reversible in all animals within 7 days Mild eye irritation potential under the conditions of this study

In the BCOP test, BAS 750 01 F did not cause ocular corrosion or severe irritation. Further than that, the IVIS score of 7.8 did not enable a prediction to be made for eye irritation potential (≤ 3 = no classification for eye irritation; > 3 but ≤ 55 = no prediction).

In a reconstructed human cornea model, BAS 750 01 F demonstrated an eye irritation potential (mean tissue viability score ≤ 60 % of negative control = irritant).

The potential of BAS 750 01 F to cause eye irritation was further assessed in an *in vivo* study in rabbits. Ocular reactions were reported from one hour until 72 hours after administration of the test material. All reactions had fully resolved by seven days. The mean scores for corneal opacity (2.0, 1.3, 1.0 for each animal) and iris lesions (1.0, 1.0, 0.7) indicate that the product meets the criteria for classification for eye irritation category 2 (H319) (in at least two of three animals, corneal opacity ≥ 1 and/or iritis ≥ 1 calculated as mean scores over 24, 48 and 72 hours).

Data on the eye irritation potential of all the ingredients of the product are available. The active substance is not an eye irritant. However, two co-formulants meet the criteria for classification for severe eye damage (H318); these comprise 1 % and 20 % of the product, respectively. Two further co-formulants, together present at a concentration of 37.6 %, are eye irritants (H319). The applicant used these data to predict that the product would meet the criteria for classification for severe eye damage (H318). On the basis of the irritant potential in the EpiOcular test and the absence of a potential for severe eye irritation in the BCOP test, the RMS proposes that the product be classified in category 2 (H319).

B.6.1.6. Skin sensitisation

The skin sensitisation potential of BASF 750 01 F has been assessed in a murine local lymph node assay.

Table B.6.1.6.1. Summary of skin sensitisation study with BAS 750 01 F

Method, Guideline, GLP status, reference	Species, strain, sex, no/group	Test substance, dose levels, duration of exposure	Results
Local lymph Node Assay OECD 429 GLP Report CP 7.1.6/1 [redacted], 2014 (2014/1170756)	Mice, CBA/Ca 5 females /group (1/group for each pre-test) Lymph nodes were pooled per animal	Concentrations: 1, 2 and 5% in acetone/olive oil (4+1, v/v) Positive control (not concurrent) = 25 % α-hexyl cinnamic acid	Erythema of the ear skin (score 1) between days 4 and 6 when 5 % applied. No local effects at 1 and 2%. S.I. values: 1 % = 0.89 2 % = 0.80 5 % = 0.94 Positive control = 7.19 Not a skin sensitiser under the conditions of this assay

Prior to the conduct of the main LLNA, three pre-tests were conducted to determine the highest non-irritant test concentration that also did not induce signs of systemic toxicity. In accordance with OECD test guideline 429, the criteria for excessive local irritation were an erythema score ≥ 3 and/or an increase in ear thickness of ≥ 25 % on any day of measurement (day 3 and day 6).

In the first pre-test, BAS 750 01 F was applied at concentrations of 50 % in acetone/olive oil and 100 % (one animal at each concentration). No signs of systemic toxicity were observed, but both mice

showed very-slight to well-defined erythema of the ear skin, visible swelling of the ears (see table below) and an increase in ear weight.

Since the ear thickness in the first pre-test was increased by ≥ 25 % , a second pre-test was performed with concentrations of 10 % and 25 %. In this, each animal exhibited an increase in ear weight. However, erythema of the ear skin and ear thickness were below the threshold for an indication of excessive irritation. Finally, a third pre-test was performed with test-material concentrations of 2 % and 5 %. The animal exposed to 5 % showed very slight erythema of the ear skin at only one time-point (within one hour after the third application). No local signs of irritation were seen in the animal treated with the 2 % concentration. Ear thicknesses were below the 25 % threshold.

Table B.6.1.6.2. Indications of local irritation in LLNA pre-tests

Concentration	Erythema score	Ear swelling increase	Ear weight increase
100 %	1 / 2	7.8 to 35.3 %	28.4 %
50 %	1 / 2	34.7 to 35.7 %	66.3 %
25 %	2	5.2 to 6.3 %	44.3 %
10 %	1 / 2	2.1 to 3.1 %	30.7 %
5 %	1	-1.1 to 5.3 %	17.1 %
2 %	-	2.1 to 3.1 %	23.8 %

On the basis of these pre-tests, concentrations of 5 %, 2 % and 1 % were selected for the main study. None of the animals showed signs of systemic toxicity at any time point. Between days 4 and 6, the animals exposed to 5 % test item showed very slight erythema of the ear skin (score 1). There were no signs of local skin irritation at 2 % and 1 %, nor was there a statistically significant increase in ear weights compared with those of the controls in any of the treated groups. Stimulation indices of 0.89, 0.80 and 0.94 were determined at concentrations of 1, 2 and 5 %, respectively.

Under the conditions of this study, therefore, the test item BAS 750 01F, when tested at concentrations up to 5 %, was not a skin sensitiser. However, the RMS questions the validity of the negative result, since the erythema scores and ear thicknesses at concentrations of 10 % and 25 % did not meet the guideline criteria for excessive local irritation. The RMS also questions the appropriateness of undertaking an *in vivo* study on this mixture when information on the co-formulants and test data predict that it would be a skin irritant, thus limiting the maximum concentration that could be applied in an animal test to investigate skin sensitisation potential; the guidance on the application of the CLP criteria cautions that the current test methods are based on the application of a maximised dose.

Furthermore, the active ingredient, which is present in the product in a concentration of approximately 10 %, was positive for skin sensitisation in a guinea-pig maximisation test. A co-formulant, present at 20 % in the product, has been predicted to be a skin sensitiser in *in vitro* tests. The applicant therefore predicted that the product would be a skin sensitiser.

The RMS proposes that BAS 750 01 F be classified for skin sensitisation category 1 (H317) on the basis of the presence of two skin sensitising ingredients (category 1) at concentrations ≥ 1 %.

B.6.1.7. Supplementary studies on the plant protection product

None available.

B.6.1.8. Supplementary studies for combinations of plant protection products

None available.

B.6.2. DERMAL ABSORPTION

The *in vitro* dermal penetration of BAS 750 F formulated as BASF 750 01 F through human skin has been investigated.

Table B.6.2.1. Summary of *in vitro* dermal penetration study

Method, guideline, GLP status, reference	Species	Test substance, dose levels, duration of exposure	Results
In vitro dermal penetration OECD 428 GLP Report CP7.3/1 & CP 7.3/2 Fabian & Landsiedel R., 2014a (214/1147839); Fabian, 2015a (2015/1005063)	Human abdominal skin, dermatomed (split thickness), thickness of 299-400 µm 6 donors Receptor fluid: ethanol / tap water Washing solution: Texapon N 70 (sodium-laurylethersulfate), 1:140 in tap water	BASF 750 01 F containing triazole-3(5)-C14-labelled BASF 750 F, radiochemical purity > 98% High dose: formulation concentrate (100 mg/ml BASF 750 F), nominal dose 1000 µg/cm^2, 14 valid diffusion cells Low dose: 1:200 spray dilution (0.5 mg/ml BASF 750 F), 5 µg/cm^2, 8 valid diffusion cells Duration of exposure = 8 hours Duration of experiment = 24 hours	High-dose concentrate = 4% Low-dose spray dilution = 8%

In an *in vitro* experiment, the dermal penetration of BAS 750 F formulated as BAS 750 01 F through human skin was determined. For this, a high dose (formulation concentrate (100 mg/mL)) and a low dose (1:200 spray dilution (0.5 mg/mL)) was applied to human dermatomed skin at 10 µL/cm². The low-dose dilution corresponded with the in-use dilution for the supported use of 1:67 to 1:200 dilution of the concentrate. The skin was mounted into Franz-type diffusion cells operated in static mode. The exposure of the skin to the test material lasted 8 hours under a semi-occlusive covering; thereafter, the skin was thoroughly washed. Samples of the receptor fluid were taken 1, 2, 4, 6, 8, 12 and 24 hours after the start of the exposure in order to determine kinetic parameters (lag phase, absorption rate and permeability constant). Prior to the experiment, the skin-sample integrity was determined by measurement of the trans-epidermal electrical resistance, the trans-epidermal water loss and visual inspection. At the end of the experiment, cells were assessed to be valid if total recoveries fulfilled guideline requirements (a total recovery per membrane of $100 \pm 10\%$) and if clearly aberrant penetration kinetics and aberrant skin wash after the 8-hour exposure period could be excluded.

Six tape strips were taken, which were pooled into two samples for analysis: tape-strip sample 1 contained the first and second tapes, and tape-strip sample 2 contained the third to sixth tapes. The six collected tape strips were considered to represent the stratum corneum.

The mean recoveries of the different compartments are presented in the table below. Eight diffusion cells were used for the spray dilution, all of which yielded valid results. For the formulation concentrate, 16 cells were used because of inconsistent results in the first run with 8 cells; taken together, 14 cells of this dose group yielded valid results (two cells showed an insufficient first skin wash [i.e. recovery was lower than the mean value of the other cells minus twice the standard deviation of these cells] and were therefore excluded). The mean lag times for the onset of dermal penetration were 2.24 and 0.96 hours for the high and low dose, respectively. In both groups, absorption was almost complete; at 12 hours, the total penetrated radioactivity recovered in the receptor medium for the concentrate and spray dilution was 84% and 86%, respectively. The solubility of BASF 750 F in the receptor fluid was demonstrated; additionally, as the maximum concentration in the receptor chamber did not exceed 10% of the saturation concentration, the solubility of the test material in the receptor fluid was not a rate-limiting step.

Table B6.2.2. Mean recovery data from the *in vitro* dermal penetration study of ^{14}C-BAS 750 F formulated as BAS 750 01 F

Dose group	**High dose (Formulation concentrate)**	**Low dose (Spray dilution 1:200)**
Target concentration [mg/mL]	100	0.5
Target dose [µg/cm²]	1000	5.0
Valid cells evaluated / cells used	14 / 16	8 / 8
	Recovery [%] Mean ± SD	Recovery [%] Mean ± SD
Unabsorbed dose		
Skin washing after 8 hours	88.09 ± 13.21	91.69 ± 6.36
Skin washing after 24 hours	5.79 ± 8.58	2.58 ± 1.72
Donor chamber wash	3.67 ± 4.37	0.73 ± 1.26
Dose associated with skin[a]		
Tape strips, 1st pool (strips 1 - 2)	0.18 ± 0.23	0.62 ± 0.43
Tape strips, 2nd pool (strips 3 - 6)	0.25 ± 0.35	0.99 ± 1.01
Skin preparation	1.43 ± 1.62	1.95 ± 0.83
Absorbed dose		
Sum receptor samples incl. wash out	0.20 ± 0.11	0.71 ± 0.17
Receptor fluid	0.27 ± 0.15	0.81 ± 0.28
Receptor chamber wash	0.03 ± 0.06	1.99 ± 1.27
Total recovery	**99.92 ± 4.41**	**102.07 ± 2.75**
Absorption essentially complete at end of study (>75% absorption within half the study duration)?	Yes	Yes
Absorption estimates when absorption essentially completed (= absorbed dose plus dose associated with skin minus all tapes)	1.93 ± 1.80	5.47± 2.29
[SD in percentage of mean]	[ca. 93]	[ca. 41]
Absorption estimates used for risk assessment [a]	**4 %**	**8 %**

[a] In accordance with the EFSA Guidance on Dermal Absorption one standard deviation was added to the mean % dermal penetration in cases where the standard deviation was ≥ 25 % of the mean value. This value was then rounded to the required number of significant figures.

The test-substance content of tape-strip sample 1 was added to the non-absorbed dose, whilst that of tape-strip sample 2 was added to the dose associated with the skin (absorbed dose).

In line with the EFSA Guidance on Dermal Absorption (EFSA Journal 2012;10(4):2665), the radioactivity from the following samples was regarded to have been absorbed.

If sample period is 24 hours and over 75 % of the total absorption (receptor fluid) occurred within half the duration of the sampling period, then

absorption = receptor fluid + receptor chamber washes + skin samples (excluding all tape strips).

High dose = 0.27 + (0.20 + 0.03) + 1.43 = 1.93 % of applied dose

Low dose = 1.99 + (0.71 + 0.81) + 1.95 = 5.47 % of applied dose

As the standard deviations exceeded 25 % of the mean absorption values, the standard deviations were added to the mean values to give the following absorption estimates.

High dose (formulation concentrate) = 1.93 + 1.8 = 3.73, rounded to **4 %**.

Low dose (1 in 200 dilution) = 5.47 + 2.29 = 7.76, rounded to **8 %**.

These dermal absorption values will be used in the risk assessment.

B.6.3. AVAILABLE TOXICOLOGICAL DATA RELATING TO CO-FORMULANTS

Confidential information.

B.6.4. EXPOSURE DATA

B.6.4.1. Operator exposure

A summary of the application parameters pertinent to the operator, bystander, resident and worker exposure assessment for 'BAS 750 01 F' are presented below.

Table B.6.4.1-1: Summary of 'BAS 750 01 F' application parameters pertinent to the operator, bystander, resident and worker exposure assessment.

'BAS 750 01 F'	
Formulation type	EC (emulsifiable concentrate), containing 100 g/L BAS 750 F
Use	Fungicide for use on cereals
Application method	Tractor-mounted/trailed field crop sprayer
Max individual dose	1.5 L product/ha (150 g a.s./ha)
Max total dose	3 L product/ha/crop (300 g a.s./ha/crop)
Application volume	100 to 300 L/ha
Max spray concentration	1.5 g a.s./L
Number of applications	2 per year
Interval between applications	14 days
Latest time of application	BBCH 69
Packaging	5 L, 10 L and 15 L containers
Classification	H317 - May cause an allergic skin reaction
Systemic AOEL	0.11 mg/kg bw/day
Systemic AAOEL	0.25 mg/kg bw/day (based on the proposed ARfD with no correction for oral absorption)
Dermal absorption	4 % for the concentrate, 8 % for the 1/200 dilution

Predicted levels of operator exposure to 'BAS 750 01 F' have been calculated using the EFSA calculator and are presented below. Exposure estimate spreadsheets are in Appendix 1.

On the basis of the classification of the product as a skin sensitizer the use of suitable protective gloves and coveralls when handling the concentrate are required.

B.6.4.1.1 Estimate of Operator Exposure Using EFSA calculator

Applications received by HSE after 1st January 2016 must reflect the European Food Standards Authority (EFSA) guidance document 'Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products[2]'. Operator exposure has therefore been calculated by the UK HSE using the EFSA Calculator. An acute exposure risk assessment for operators has been conducted on the basis that the active substance BAS 750 F is acutely toxic and for which a surrogate AAOEL has been proposed

A standard bodyweight of 60 kg and a work rate of 50 ha/day with a duration of exposure to the active BAS 750 F for 8 hours is assumed. Dermal absorption values for BAS 750 F of 4% for the concentrate and 8% for the spray solution have been used as proposed by UK HSE. The results can be summarised as follows, with the full spreadsheets presented in Appendix 1 (Estimate 1).

Table B.6.4.1.1-1 EFSA calculator estimate of acute exposure to operators while applying 'BAS 750 01 F' through field crop boom sprayer

		BAS 750 F	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg/day)**	**% of systemic AAOEL**
Tractor mounted boom spray application outdoors to low crops			
Application rate:		0.15 kg a.s./ha	
Spray application (AOEM**;** 95th percentile) Body weight: 60 kg	work wear mixing, loading and application	0.0733	29 %

Based on the EFSA calculator, the predicted level of acute exposure to an operator is 29 % of the systemic AAOEL of 0.25 mg/kg bw/day without the use of PPE. The predicted acute exposure to an operator is within acceptable limits.

[2] European Food Safety Authority (2014). Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products, EFSA Journal 2014;12(10):3874. March 2015 version.

Table B.6.4.1.1-2 EFSA calculator estimate of longer term exposure for operators applying 'BAS 750 01 F' through field crop boom sprayer

		BAS 750 F	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**
Tractor mounted boom spray application outdoors to low crops			
Application rate:		0.15 kg a.s./ha	
Spray application (AOEM**;** 75th percentile) Body weight: 60 kg	work wear mixing, loading and application	0.0173	16 %

Based on the EFSA calculator and using 'BAS 750 01 F' as directed, the predicted longer term exposure to an operator is 16 % of the systemic AOEL of 0.11 mg/kg bw/day without the use of PPE. The predicted longer term exposure to an operator for application via tractor mounted boom sprayer is within acceptable limits.

'BAS 750 01 F' is classified with respect to human health. The classification and resulting PPE requirements are given below.

H Phrase	PPE
H317 May cause an allergic skin reaction	Gloves and coveralls when handling the concentrate

On the basis of the exposure estimates produced by the EFSA calculator and from the classification of 'BAS 750 01 F', the following operator protection phrases are required:

- Operators must wear suitable protective clothing (coveralls) and suitable protective gloves when handling the concentrate.

B.6.4.2. Bystander Exposure

A bystander exposure assessment has been undertaken using the EFSA calculator (95th percentile) exposure values for comparison with the AAOEL of 0.25 mg/kg bw/d.

Table B.6.4.2-1 EFSA calculator estimate of bystander exposure from the application of 'BAS 750 01 F'

		BAS 750 F	
Model data		**Total absorbed dose (mg/kg bw/day)**	**% of systemic AAOEL**
Tractor mounted boom spray application outdoors to low crops Buffer zone: 2-3(m) Drift reduction technology: not applicable DT_{50}: 30 days DFR: 3 µg/cm^2/kg a.s./ha Interval between treatments: 14 days			
Number of applications and application rate:		2 x 0.15 kg a.s./ha	
Bystander child Body weight: 10 kg	Drift (95th perc.)	0.0074	3 %
	Vapour (95th perc.)	0.0011	<1 %
	Deposits (95th perc.)	0.0015	1 %
	Re-entry (95th perc.)	0.0035	1 %
Bystander adult Body weight: 60 kg	Drift (95th perc.)	0.0020	1%
	Vapour (95th perc.)	0.0002	1 %
	Deposits (95th perc.)	0.0004	<1 %
	Re-entry (95th perc.)	0.0019	1 %

Full details of the calculations can be found in Appendix 1

Acute exposure to the active BAS 750 F after application of the product 'BAS 750 01 F' via tractor mounted boom sprayer for a child and adult bystander from spray drift, vapour, surface deposits and re-entry into treated crops are within acceptable limits.

B.6.4.3. Resident exposure

Table B.6.4.3-1 EFSA calculator resident exposure from the application of 'BAS 750 01 F'

Model data		BAS 750 F	
		Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Tractor mounted boom spray application outdoors to low crops Buffer zone: 2-3(m) Drift reduction technology: not applicable DT_{50}: 30 days DFR: 3 µg/cm^2/kg a.s./ha Interval between treatments: 14 days			
Number of applications and application rate:		2 x 0.15 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75th perc.)	0.0033	3 %
	Vapour (75th perc.)	0.0011	1 %
	Deposits (75th)perc.)	0.0005	<1 %
	Re-entry (75th perc.)	0.0035	3 %
	Sum (mean)	0.0060	5 %
Resident adult Body weight: 60 kg	Drift (75th perc.)	0.0008	1 %
	Vapour (75th perc.)	0.0002	<1 %
	Deposits (75th perc.)	0.0001	<1 %
	Re-entry (75th perc.)	0.0019	2 %
	Sum (mean)	0.0022	2 %

Full details can be found in Appendix …..

For application of 'BAS 750 01 F' via tractor mounted boom sprayer the predicted longer term exposure to a child and adult resident from spray drift, vapour, surface deposits, re-entry into treated crops and sum of all pathways are within acceptable limits.

B.6.4.4. Worker exposure

An assessment of exposure to workers compared to the AOEL has been conducted using the EFSA calculator. In the absence of suitable data and an agreed methodology it is not possible to undertake an acute assessment of exposure to workers using the EFSA calculator therefore only an assessment of long term exposure has been undertaken

Table B.6.4.4-1 EFSA calculator estimate of exposure to workers from the application of 'BAS 750 01 F'

		BAS 750 F	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**
Inspection, irrigation Outdoor Work rate: 2 hours/day DT_{50}: 30 days Initial DFR: 3 µg/cm^2/kg a.s./ha Intervals between treatements: 14 days			
Application rate:		2 x 0.15 kg a.s./ha	
Body weight: 60 kg	work wear (arms, body and legs covered) TC: 1400 cm^2/person/h	0.0029	3%

Full details can be found in Appendix ….

Estimates using the EFSA calculator predict that the proposed use of 'BAS 750 01 F' for an unprotected worker inspecting treated crops will result in 2% of the AOEL of BAS 750 F. The predicted systemic exposure to re-entry workers is within acceptable limits.

B.6.5. EXPOSURE AND RISK ASSESSMENT

Exposure to operators

Estimates based on surrogate data contained in the EFSA calculator predict that the proposed use of 'BAS 750 01 F' through field crop sprayers will result in a level of long term systemic exposure equivalent to 16% of the AOEL for an operator without the need for PPE. For acute exposure to an operator during use of the product 'BAS 750 01 F', the level of systemic exposure is equivalent to 29% of the AAOEL for an operator not wearing PPE.

On the basis of these estimates and considering the classification of the product as containing an active that may cause an allergic skin reaction (H317), the proposed use of 'BAS 750 01 F' is considered to be acceptable subject to the following operator protection requirement:

- Operators must wear suitable protective gloves and coveralls when handling the concentrate.

Exposure to bystanders

An assessment of acute exposure to bystanders compared to the AAOEL has been conducted using the EFSA calculator. The EFSA calculator predicts that the proposed use of 'BAS 750 01 F' will result in the following levels of systemic exposure to BAS 750 F for unprotected bystanders:

Routes of exposure		**BAS 750 F**
		% of systemic AAOEL
Bystander child Body weight: 10 kg	Drift (95th perc.)	3 %
	Vapour (95th perc.)	<1 %
	Deposits (95th perc.)	1 %
	Re-entry (95th perc.)	1 %
Bystander adult Body weight: 60 kg	Drift (95th perc.)	1%
	Vapour (95th perc.)	<1 %
	Deposits (95th perc.)	<1 %
	Re-entry (95th perc.)	1 %

On the basis of these estimates, the level of acute exposure for unprotected bystanders resulting from the proposed use of 'BAS 750 01 F' is considered to be acceptable.

Exposure to residents

An assessment of long term exposure to residents compared to the AOEL has been conducted using the EFSA calculator. The EFSA calculator predicts that the proposed use of 'BAS 750 01 F' will result in the following levels of systemic exposure to BAS 750 F for unprotected residents:

Routes of exposure		**BAS 750 F**
		% of systemic AOEL
Resident child Body weight: 10 kg	Drift (75th perc.)	3 %
	Vapour (75th perc.)	1 %
	Deposits (75th)perc.)	<1 %
	Re-entry (75th perc.)	3 %
	Sum (mean)	5 %
Resident adult Body weight: 60 kg	Drift (75th perc.)	1 %
	Vapour (75th perc.)	<1 %
	Deposits (75th perc.)	<1 %
	Re-entry (75th perc.)	2 %
	Sum (mean)	2 %

On the basis of these estimates, the level of long term exposure for unprotected residents resulting from the proposed use of 'BAS 750 01 F' is considered to be acceptable.

Exposure to workers

Estimates using EFSA calculator predict that the proposed use of 'BAS750 01 F' will result in a level of systemic exposure to BAS 750 F equivalent to 3 % of the AOEL for an unprotected worker entering treated areas to carry out crop inspection activities.

On the basis of these estimates, the level of exposure for unprotected workers entering and handling crops treated with 'BAS 750 01 F' is considered to be acceptable.

B.6.6. REFERENCES RELIED ON

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KCP 7.1.1/1	[redacted]	2015 a	BAS 750 01 F - Acute oral toxicity study in rats 2014/1170774 [redacted]. yes Unpublished	Yes	Yes	Data for first Approval Not granted – study not required for decision on classification & labelling.	BASF	N.A.
KCP 7.1.2/1	[redacted]	2015 b	BAS 750 01 F - Acute dermal toxicity study in rats 2014/1170776 [redacted]	Yes	Yes	Data for first Approval Not granted – study not required for decision on classification & labelling.	BASF	N.A.

			yes Unpublished					
KCP 7.1.3/1	[redacted]	2014 a	BAS 750 01 F: 4-hour acute inhalation toxicity study in the rat 2014/1170778 [redacted] yes Unpublished	Yes	Yes	Data for first Approval	BASF	N.A.

KCP 7.1.4/1	Wareing B.	2014 a	Summary report - BAS 750 01 F - EpiDerm skin corrosion test 2014/1127439 BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep. no Unpublished	No	No	Not applicable	BASF	N.A.
KCP 7.1.4/2	Wareing B.	2014 b	Summary report - BAS 750 01 F - EpiDerm skin irritation test 2014/1127441 BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep. no Unpublished	No	No	Not applicable	BASF	N.A.
KCP 7.1.4/3	[redacted]	2015 c	BAS 750 01 F - Acute dermal irritation / corrosion in rabbits 2014/1170779 [redacted]. yes Unpublished	Yes	Yes	Data for first Approval Not granted – study not required for decision on classification & labelling.	BASF	N.A.

KCP 7.1.5/1	Wareing B.	2014 c	Summary report - BAS 750 01 F - Bovine corneal opacity and permeability test (BCOP test) 2014/1127440 BASF SE, Ludwigshafen / Rhein, Germany Fed.Rep. no Unpublished	No	No	Not applicable	BASF	N.A.
KCP 7.1.5/2	Remmele M.	2014 a	Summary report - BAS 750 01 F - EpiOcular eye irritation test 2014/1083341 BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep. no Unpublished	No	No	Not applicable	BASF	N.A.
KCP 7.1.5/3	[redacted]	2015 d	BAS 750 01 F - Acute eye irritation in rabbits 2014/1170780 [redacted] yes Unpublished	Yes	Yes	Data for first Approval Not granted – study not required for decision on classification & labelling.	BASF	N.A.
KCP 7.1.6/1	[redacted]	2014 a	BAS 750 01 F - Skin sensitisation: Local lymph node assay	Yes	Yes	Data for first Approval Not granted – study not	BASF	N.A.

			2014/1170756 [redacted] yes Unpublished			required for decision on classification & labelling.		

APPENDIX 1: OPERATOR EXPOSURE CALCULATIONS

Estimate 1: EFSA calculator estimates of exposure for operators applying product containing 'BAS 750 F': field crop sprayer / no PPE

Substance	BAS 750 F	Formulation = Soluble concentrates, emulsifiable concentrate, etc.	Application rate-0.15 kg a.s. /ha	Spray dilution = 1.5 g a.s./l	Vapour pressure = low volatile substances having a vapour pressure of <5*10-3Pa
Scenario	Cereals / Outdoor / Downward spraying / Vehicle-mounted			Buffer = 2-3	Number applications = 2, Application interval = 14 days
Percentage Absoprtion	Dermal for product = 4	Dermal for in use diluation = 8	Oral = 100	Inhalation = 100	
RVNAS	0.11 mg/kg bw/day		RVAAS	0.25 mg/kg bw/day	
DFR	3 µg a.s./cm2 per kg a.s./ha		DT50	30 days	

Operator Model		Mixing, loading and application AOEM			
Potential exposure	Longer term systemic exposure mg/kg bw/day		0.0278	% of RVNAS	25.31%
	Acute systemic exposure mg/kg bw/day		0.1630	% of RVAAS	65.21%
Mixing and Loading		Gloves = No	Clothing = Work wear - arms, body and legs covered	RPE = None	Soluble bags = No
Application		Gloves = No	Clothing = Work wear - arms, body and legs covered	RPE = None	Closed cabin = No
Exposure (including PPE options above)	Longer term systemic exposure mg/kg bw/day		0.0173	% of RVNAS	15.76%
	Acute systemic exposure mg/kg bw/day		0.0733	% of RVAAS	29.33%

Worker - Inspection, irrigation	Potential exposure mg/kg bw/day	0.0259	% of RVNAS	23.50%
	Working clothing mg/kg bw/day	0.0029	% of RVNAS	2.63%
	Working clothing and gloves mg/kg bw/day		% of RVNAS	

Resident - child	Spray drift (75th percentile) mg/kg bw/day	0.0033	% of RVNAS	2.96%
	Vapour (75th percentile) mg/kg bw/day	0.0011	% of RVNAS	0.97%
	Surface deposits (75th percentile) mg/kg bw/day	0.0005	% of RVNAS	0.46%
	Entry into treated crops (75th percentile) mg/kg bw/day	0.0035	% of RVNAS	3.17%
	All pathways (mean) mg/kg bw/day	0.0060	% of RVNAS	5.48%
Resident - adult	Spray drift (75th percentile) mg/kg bw/day	0.0008	% of RVNAS	0.70%
	Vapour (75th percentile) mg/kg bw/day	0.0002	% of RVNAS	0.21%
	Surface deposits (75th percentile) mg/kg bw/day	0.0001	% of RVNAS	0.13%
	Entry into treated crops (75th percentile) mg/kg bw/day	0.0019	% of RVNAS	1.76%
	All pathways (mean) mg/kg bw/day	0.0022	% of RVNAS	2.04%

Bystander - child	Spray drift (95th percentile) mg/kg bw/day	0.0074	% of RVAAS	2.98%
	Vapour (95th percentile) mg/kg bw/day	0.0011	% of RVAAS	0.43%
	Surface deposits (95th percentile) mg/kg bw/day	0.0015	% of RVAAS	0.59%
	Entry into treated crops (95th percentile) mg/kg bw/day	0.0035	% of RVAAS	1.40%
Bystander - adult	Spray drift (95th percentile) mg/kg bw/day	0.0020	% of RVAAS	0.80%
	Vapour (95th percentile) mg/kg bw/day	0.0002	% of RVAAS	0.09%
	Surface deposits (95th percentile) mg/kg bw/day	0.0004	% of RVAAS	0.17%
	Entry into treated crops (95th percentile) mg/kg bw/day	0.0019	% of RVAAS	0.78%

Operator exposure for BAS 750 01 F outdoor spray applications

Application rate of active substance	0.15	kg a.s./ha	*i_AppRate*
Assumed area treated	50	ha/day	*d_AreaTreated*
Amount of active substance applied	7.5	kg a.s./day	*i_AmoutAS*
Dermal absorption of the product	4.00%		*i_AbsorpProduct*
Dermal absorption of in-use dilution	8.00%		*i_AbsorInuse*
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.		
Indoor or Outdoor application	Outdoor		
Application method	Downward spraying		
Application equipment	Vehicle-mounted		
Season	not relevant		

OutdoorSoluble concentrates, emulsifiable concentrate, etc.Downward sprayingVehicle-mounted

	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75th centile	95th centile		
Mixing and loading	Hands	22909	85448	AOEM	
	Body	14704	129332	AOEM	
	Head	389	2134	AOEM	
	Protected hands (gloves)	128	1486	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	142	1097	AOEM	
	Protected head (hood and face shield)	6	121	AOEM	
	Inhalation	7	30	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	

	Exposure values	µg exposure/day applied		Reference	Comment
		75th centile	95th centile		
Application	Hands	1112	10024	AOEM	
	Body	622	3206	AOEM	
	Head	29	89	AOEM	
	Protected hands (gloves)	127	4216	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	17	42	AOEM	
	Inhalation	3	9	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	1.6707814	1.0398962	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.0278464	0.0173316	
% of RVNAS	25.31%	15.76%	
Acute			
Total systemic exposure from mixing, loading and application (mg a.s./day)	9.7815074	4.3989491	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.1630251	0.0733158	
% of RVAAS	65.21%	29.33%	

2. Longer term exposure

2.1 Mixing and loading

	Systemic exposure [µg a.s. /day]	Systemic exposure [µg a.s./kg bw/day]	Formula
Without RPE/PPE			
Hands	916.3648112	15.2727469	*D15*i_AbsorpProduct*
Body	588.1617874	9.8026965	*D16*i_AbsorpProduct*
Head	15.5650763	0.2594179	*D17*i_AbsorpProduct*
Inhalation	6.7424577	0.1123743	*D21*i_AbsorpInhalation*
Sum	1526.8341326	25.4472355	
With RPE/PPE (as selected above)			
Hands	916.3648112	15.2727469	*D18*i_AbsorpProduct*
Body	5.6712402	0.0945207	*D19*i_AbsorpProduct or D15*i_AbsorpProduct*F24*
Head	15.5650763	0.2594179	*D20*i_AbsorpProduct or D17*i_AbsorpProduct*F25*
Inhalation	6.7424577	0.1123743	*D21*i_AbsorpInhalation*G25*
Sum	944.3435854	15.7390598	
Water soluble	944.3435854	15.7390598	*C70*F26*

2.2 Application

	Systemic exposure [µg a.s. /day]	Systemic exposure [µg a.s./kg bw/day]	Formula
Without RPE/PPE			
Hands	88.9940279	1.4832338	*D30*i_AbsorpInuse*
Body	49.7596028	0.8293267	*D31*i_AbsorpInuse*
Head	2.3518093	0.0391968	*D32*i_AbsorpInuse*
Inhalation	2.8418233	0.0473637	*D35*i_AbsorpInhalation*
Sum	143.9472634	2.3991211	
With RPE/PPE (as selected above)			
Hands	88.9940279	1.4832338	*D33*i_AbsorpInuse*
Body	1.3649899	0.0227498	*D34*i_AbsorpInuse or D31*i_AbsorpInuse*F38*
Head	2.3518093	0.0391968	*D32*i_AbsorpInuse*F39*
Inhalation	2.8418233	0.0473637	*D35*i_AbsorpInuse*G39*
Sum	95.5526504	1.5925442	

Worker exposure to BAS 750 F

Crop type	Cereals		
Indoor or outdoor	Outdoor		
Application method	Downward spraying		
Application equipment	Vehicle-mounted		
Worker's task	Inspection, irrigation		
Main body parts in contact with foliage	Hand and body		
Application rate of active substance	0.15	kg a.s./ha	*I_AppRate*
Number of applications	2		*I_AppNo*
Interval between multiple applications	14	days	*I_AppInt*
Half-life of active substance	30	days	*d_HalflifeAS*
Multiple application factor	1.7		*d_MAF*
Dermal absorption of the product	4.00%		*I_AbsorpProduct*
Dermal absorption of the in-use dilution	8.00%		*I_AbsorpInuse*
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.45	µg a.s./cm^2	*d_DFR*
Working hours	2	hr	*d_WorkHr*
Dermal transfer coefficient - Total potential exposure	12500	cm^2/hr	*d_DermTcUCV*
Dermal transfer coefficient - arms, body and legs covered	1400	cm^2/hr	*d_DermTcCV1*
Dermal transfer coefficient - hands, arms, body and legs covered	no TC available for this assessment	cm^2/hr	*d_DermTcCV2*
Inhalation transfer coefficient for automated applications	NA	ha/hr*10^(-3)	*d_InhalTcAut*
Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10^(-3)	*d_InhalTcCut*
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	ha/hr*10^(-3)	*d_InhalTcSort*

Resident exposure to BAS 750 F

Resident exposure for BAS 750 01 F

Croptype	Cereals	
Application method	Downward spraying	
Application equipment	Vehicle-mounted	
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	
Buffer strip	2-3	m
Application rate of the product	0.15	kg a.s./ha
Concentration of active substance (in-use dilution for liquid applications)	1.5	g a.s./l
Dermal absorption of product	4.00%	
Dermal absorption of in-use dilution	8.00%	
Oral absorption	100.00%	
Dislodgeable foliar residue (i_AppRate* i_DFR)	0.45	µg a.s./cm^2
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa	Pa
Concentration in air	0.001	mg/m^3
Resident dermal spray drift exposure 75th percentile - adult	0.47	ml spray dilution/person
Resident dermal spray drift exposure 75th percentile - child	0.327	ml spray dilution/person
Resident inhal. spray drift exposure 75th percentile - adult	0.00010	ml spray dilution/person
Resident inhal. spray drift exposure 75th percentile - child	0.00022	ml spray dilution/person
Resident dermal spray drift exposure mean - adult	0.22318	ml spray dilution/person
Resident dermal spray drift exposure mean - child	0.18	ml spray dilution/person
Resident inhal. spray drift exposure mean - adult	0.00009	ml spray dilution/person
Resident inhal. spray drift exposure mean - child	0.00017	ml spray dilution/person
Exposure duration dermal	2	hours
Exposure duration inhalation	24	hours
Exposure duration entry into treated crops	0.25	hours
Light clothing adjustment factor	18.0%	
Breathing rate adult	0.23	m^3/day/kg
Breathing rate child (1-3 year old)	1.07	m^3/day/kg
Drift percentage on surface (75th percentile)	5.60%	
Drift percentage on surface (mean)	4.10%	
Turf transferable residues percentage	5.00%	
Transfer coeff. of surface deposits-adult	7300	cm^2/hour
Transfer coeff. of surface deposits-child (1-3 year old)	2600	cm^2/hour
Saliva extraction percentage	50.00%	
Surface area of hands mouthed	20	cm^2
Frequency of hand to mouth activity	9.5	events/hour
Ingestion rate for mouthing of grass per day	25	cm^2
Dislodgeable residues percentage transferability for object to mouth	20.00%	
Transfer coefficient for entry into treated crops (75th percentile) - adult	7500	cm^2/h
Transfer coefficient for entry into treated crops (75th percentile) - child	2250	cm^2/h
Transfer coefficient for entry into treated crops (mean) - adult	5980	cm^2/h
Transfer coefficient for entry into treated crops (mean) - child	1794	cm^2/h

1. Total

1.1 1-3 year old child

	Spray drift (75th percentile)	Vapour (75th percentile)	Surface deposits (75th percentile)	Entry into treated crops (75th percentile)	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.0325068	0.0107000	0.0051109	0.0349036	0.0602387
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0032507	0.0010700	0.0005111	0.0034904	0.0060239
% of RVNAS	2.96%	0.97%	0.46%	3.17%	5.48%

1.2 Adult

	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.0463980	0.0138000	0.0084555	0.1163453	0.1348525
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0007733	0.0002300	0.0001409	0.0019391	0.0022475
% of RVNAS	0.70%	0.21%	0.13%	1.76%	2.04%

Bystander exposure to BAS 750 F

Croptype	Cereals		
Application method	Downward spraying		
Application equipment	Vehicle-mounted		*i_AppEquip*
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.		
Application rate of the product	0.15	kg a.s./ha	*i_AppRate*
Buffer strip	2-3	m	*i_Buffer*
Concentration of active substance (in-use dilution for liquid applications)	1.5	g a.s./l	*d_ConcAS*
Dermal absorption of product	4.00%		*i_AbsorpProduct*
Dermal absorption of in-use dilution	8.00%		*i_AbsorpInuse*
Oral absorption	100.00%		*i_AbsorpOralInuse*
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.45	µg a.s./cm^2	*d_DFR*
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa	Pa	*i_Volat*
Concentration in air	0.001	mg/m^3	*d_AirCon*
Bystander dermal spray drift exposure - adult	1.21	ml spray dilution/person	
Bystander dermal spray drift exposure - child	0.74	ml spray dilution/person	
Bystander inhal. spray drift exposure - adult	0.00050	ml spray dilution/person	
Bystander inhal. spray drift exposure - child	0.00112	ml spray dilution/person	
Exposure duration	2	hours	*d_ByExpDur*
Exposure duration entry into treated crops	0.25	hours	*d_ExpDurTreatCrop*
Light clothing adjustment factor	18.0%		*d_ClothAF*
Breathing rate adult	0.23	m^3/kg bw/day	*d_BreathRAd*
Breathing rate child (1-3 year old)	1.07	m^3/kg bw/day	*d_BreathRCh*
Drift percentage on surface (90th percentile)	8.50%		
Turf transferable residues percentage	5.00%		*d_Turf*
Transfer coeff. of surface deposits-adult	14500	cm^2/hour	*d_ByTCAd*
Transfer coeff. of surface deposits-child (1-3 year old)	5200	cm^2/hour	*d_ByTCCh*
Saliva extraction percentage	50.00%		*d_SalExt*
Surface area of hands mouthed	20	cm^2	*d_AreaHM*
Frequency of hand to mouth activity	20	events/hour	*d_ByFreqHM*
Ingestion rate for mouthing of grass per day	25	cm^2	*d_MouthGrass*
Dislodgeable residues percentage transferability for object to mouth	20.00%		*d_DRP*
Transfer coefficient for entry into treated crops - adult	7500	cm^2/h	*d_TcEntryAd*
Transfer coefficient for entry into treated crops - child	2250	cm^2/h	*d_TcEntryCh*

1. Total

1.1 1-3 year old child

	Spray drift	Vapour	Surface deposits	Entry into treated crops
Total systemic exposure (mg a.s./day)	0.0744960	0.0107000	0.0146362	0.0349036
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0074496	0.0010700	0.0014636	0.0034904
% of RVAAS	2.98%	0.43%	0.59%	1.40%

1.2 Adult

	Spray drift	Vapour	Surface deposits	Entry into treated crops
Total systemic exposure (mg a.s./day)	0.1198140	0.0138000	0.0254926	0.1163453
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0019969	0.0002300	0.0004249	0.0019391
% of RVAAS	0.80%	0.09%	0.17%	0.78%